

REMARKS

Applicant respectfully requests reconsideration of this application in view of the above amendments and the following remarks.

Claims 1 – 4, 7 and 8 have been amended. New claims 9 and 10 have been added. Claims 1 – 4, and 7 – 10 are presented for further prosecution on the merits.

I. SUMMARY OF OFFICE ACTION

The Examiner rejected claims 1 – 4, 7 and 8 under 35 U.S.C. § 112, first paragraph, because the Examiner believes that they fail to comply with the written description requirement.

The Examiner rejected claim 1 under 35 U.S.C. §112, second paragraph, because the Examiner believes that it fails to particularly point out and distinctly claim the subject matter. Specifically, the Examiner has questioned the “operation of a test strip.”

The Examiner rejected claim 3 under 35 U.S.C. §112, second paragraph, because the Examiner believes that it fails to particularly point out and distinctly claim the subject matter. Specifically, the Examiner questioned “enhancing the function of the test strip.”

The Examiner rejected claim 4 under 35 U.S.C. §112, second paragraph, because the Examiner believes that it fails to particularly point out and distinctly claim the subject matter. Specifically, the Examiner is not sure if claim 4 is directed towards a test strip or a method of use.

The Examiner rejected claim 8 under 35 U.S.C. §112, second paragraph, because the Examiner believes that it fails to particularly point out and distinctly claim the subject matter. Specifically, the Examiner is unsure of the location of the swing (sic) hinge; further, the Examiner was unsure how the addition of a hinge limits claim 4.

II. APPLICANT’S INVENTION

Applicant’s invention is an improved test strip that prevents the separation of the various layers of the test strip which increases the flow of the specimen being tested by stretching the micro-pores. Applicant’s test strip significantly reduces the possibility that the multiple layers of a test strip will separate which ensures that a sufficient volume of the specimen is wicked up the

test strip and delivered to the chemical portion of the test strip, thereby ensuring an accurate test of the specimen.

III. REPLY TO OFFICE ACTION

The Examiner rejected claims 1 – 4, 7 and 8 under 35 U.S.C. § 112, first paragraph, because the Examiner believes that Applicant's specification does not disclose that flexing is made in a manner that avoids folds.

Applicant respectfully submits that it is well-known to those skilled in the art of test strips that:

- A) test strips are made of multiple layers of material;
- B) test strips have a first end that is dipped into the specimen and an opposite end that is chemically impregnated so that the test strip will turn a specific color in the presence of a compound that the test strip is designed to detect;
- C) test strips are designed to wick a liquid specimen from the first end to the end that is chemically impregnated;
- D) manufacturers of test strips usually require that the test strips be placed flat (whether in the horizontal plane or the vertical plane), without bending, to prevent the separation of layers of material; and
- E) the separation of the layers of material (either by bending, physical damage, or by improper handling/storage of the test strips) usually results in an inaccurate testing of the specimen because of the uneven flow/delivery of the specimen to the chemically impregnated end of the test strip.

Applicant has amended Claim 1 to clearly indicate that it improves the functionality of the test strip by bending the test strip in such a manner that prevents the layers of the test strip from separating. Support for this claim amendment can be found in Applicant's description at page 15, lines 13-16.

In view of the above, the Examiner's rejection under 35 U.S.C. § 112, first paragraph, is traversed.

Knappe (cited by the Examiner in a previous Office Action) indicates that the flexing does not have a positive benefit because of the compressing of the inner side of the test strip and the stretching of the outer side of the test strip. According to Knappe, since test strips are comprised of multiple layers that are stacked on top of one another, the layers on the inner side forms folds that pull away from the outer layers of the test strip. (See Knappe at column 4, lines 51-67.) Applicant submits that one skilled in the art after reading both the Knappe patent and Applicant's description would readily understand that these documents describe the identical problem.

A novice without any experience in the field of test strips when provided with a description of test strips would immediately understand their construction when told that they are made of multiple layers stacked on top of one another like a sandwich. Again, a novice would understand that Knappe's description of what would happen to a test strip once it is bent (i.e., the inner side would pull away from the outer side and form folds), is nearly identical to Applicant's description of the layers being separated when the test strip is bent. Applicant is at a loss as to why the Examiner, who has experience in the field of test strips, is having trouble understanding the concept of the separation of layers – especially when this is a well-known result when test strips are bent.

Although Applicant has not expressly used the term “folds” as used in Knappe, a person skilled in the art would immediately recognize that both documents are describing the same problem – that is, that the operation (or functionality) of the test strip is decreased because the test strip is no longer one compact multi-layer unit (instead, at least the section that has separated, resembles a plurality of single-layered units).

Manufacturers of test strips guarantee that their test strips will be able to detect the presence of certain substances at a specific level (for example, an illegal drug that appears in X parts per million of the specimen). However, manufacturers of test strips do not guarantee this result if the test strip is damaged (e.g., such as when the test strip is bent) because the chemicals impregnated into the test strips may not receive a sufficient quantity of the specimen to react with the chemicals. The separation or formation of folds in the test strip interferes with the flow of the specimen from the end dipped into the specimen to the end with the chemicals. (Other

factors may also interfere with the flow of the specimen, such as when the test strip is exposed to a high humidity for an extended period of time before use.)

The Examiner rejected Claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter; specifically, the Examiner asked, “What does operation of a test strip mean?”

Applicant has amended claim 1 by replacing the word “operation” in the preamble with the word ‘functionality.’ However, Applicant wishes to address the question posed by the Examiner.

As in virtually any device that has some use or purpose, its “operation” is the “performance of a practical work or of something involving the practical application of principles or processes.” See Meriam-Websters OnLine Dictionary at www.m-w.com © 2005.

A test strip has primarily one job, function, principle, process or operation: convey to an observer the presence of a substance (e.g., a drug) in the specimen being tested. Test strips accomplish this function by wicking or absorbing a portion of the specimen to be tested into one end of the test strip; drawing that specimen portion up the length of the test strip to the section of the test strip on which the various chemicals are located; and, if the substance which is being tested for is present, turning a specific color so that the observer can positively identify the existence of said substance.

Applicant respectfully submits that a test strip is operational in the same manner that paint, gum or an article of clothing can be operational or functional. By wearing an article of clothing, the user is protected from the cold, rain, or sunlight. The functionality or “operation” of the article of clothing can be improved by adding insulation to improve its ability to protect the user from cold temperatures, or treating it with a water-repellant chemical to improve its ability to protect the user from rain.

Clearly, the functionality of a test strip is when it is being used to determine the presence (or absence) of a substance (usually a drug). Therefore, Applicant respectfully traverses the rejection of claim 1 under 35 U.S.C. §112, second paragraph.

The Examiner rejected Claim 3 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. Specifically, the Examiner asked, “What does enhancing the function of a test strip mean?”

A method or object that improves the accuracy of a test strip, the ease of reading the results of the test strip, or the speed of obtaining the results would all be considered as having improved the operation or functionality of a test strip.

Applicant submits that he has “enhanced the function of a test strip” by improving the accuracy and lateral flow, especially when the test strip undergoes a physical transformation (in this case being bent so that it may more conveniently be used with Applicant’s specimen tester).

Applicant’s invention allows the test strip to be bent when placed inside Applicant’s cassette cover. The top or chemical portion of the test strip lays flat (i.e., in the horizontal plane) in Applicant’s specimen tester thus allowing an observer to relatively quickly and accurately read the results. (In other specimen testers, the test strip may be vertical or have some other orientation.) The bottom portion of the test strip is positioned in the vertical plane which allows the test strip to be more easily controlled as it is dipped into the specimen (or as a portion of the specimen is allowed into the chamber where the test strip is located). Applicant also determined that bending of the test strip with the controlled pressure applied by a collar increases the lateral flow of the specimen along the length of the test strip.

In view of the above, Applicant has traversed the Examiner’s rejection of claim 3 under 35 U.S.C. §112, second paragraph.

The Examiner rejected claim 4 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, specifically, the Examiner noted that claim 4 recited a test strip (an apparatus) and a method.

Applicant has amended claim 4 and believes that it properly recites a test strip.

The Examiner rejected claim 8 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter. The Examiner states that the location of the “swing” (sic) hinge is not clear. Applicant believes that the Office Action contained a typographical error and the Examiner meant “living” hinge.

Applicant has amended claim 8 and added new claims 9 and 10 which clearly position the collar with the living hinge.

IV. CONCLUSION

The Examiner raised non-art issues in the outstanding Office Action. Applicant has made claim amendments in order to address the non-art issues and not as a result of any art cited by the Examiner. In fact, the Examiner did not cite any art in the last Office Action.

Should the Examiner have any questions regarding this application, he is invited to telephone the undersigned in order to expedite the examination procedure.

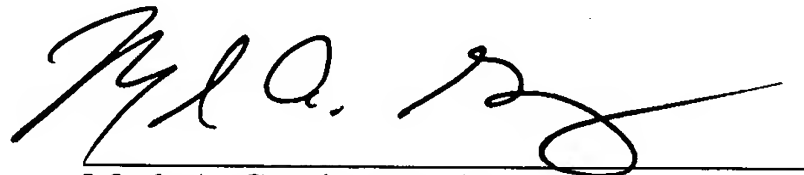
Enclosed is a self-addressed, postage pre-paid postcard for the U.S. Patent and Trademark Office to date stamp in order to acknowledge receipt of this communication.

Applicant believes that he has addressed all of the issues raised by the Examiner in the last Office Action. In view of the above amendments and Remarks, Applicant respectfully requests reconsideration of the present application and the early issuance of a Notice of Allowance for claims 1– 4 and 7 – 10.

Respectfully submitted,

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Date: 11 OCTOBER 2005



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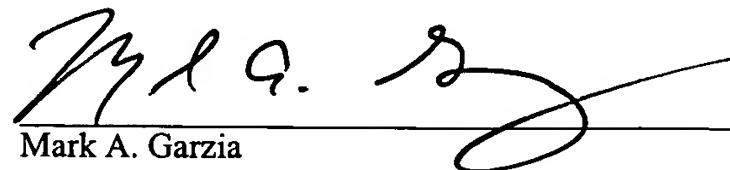
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CERTIFICATE OF MAILING

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11 OCTOBER 2005

Date



Mark A. Garzia